

# Office of Epidemiology Laboratory Screening in Local Health Departments



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STD Surveillance, Operations & Data  
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## Revision History

[illegible]

## **Purpose**

This document includes information for clinical personnel responsible for the collection and transport of specimens for reportable conditions. Specimen analysis, outcome, diagnosis, and therapeutic decisions are highly sensitive to deviations in collection method, container, transportation, and storage; therefore, all personnel in contact with specimens must ensure the proper collection, preparation, and transportation of specimens to the laboratory.

## **Supply Ordering**

To order specimen kits, use the LabCorp order form provided to your site. If the local agency conducts other laboratory testing through LabCorp, follow local procedures.

## **Eligibility**

The clinician should obtain a thorough sexual history. Client-reported exposure, regardless of condom use, should inform screening. Ascertaining specific sexual activities and recent partners during the sexual health history will guide clinical decisions. A resource for taking a complete sexual health history is available at: <https://www.cdc.gov/std/treatment/sexualhistory.pdf>.

Providers caring for transgender men and women should have knowledge of their patients' current anatomy and patterns of sexual behavior before counseling them about STD and HIV prevention. Additional information about caring for transgender persons is available at <https://www.cdc.gov/lgbthealth/transgender.htm>.

## **Completing the Requisition Form**

Refer to billing guidance for patients attending STD clinics; billing guidance is available at: <http://vdhweb.vdh.virginia.gov/community-health-services/sti-billing-transition/>.

If a test for a non-reportable condition is written on the "Office of Epidemiology" form, the test charge will be sent back to the "General Account" at the end of the month.

## **Collection of the Blood Specimen**

All blood draws must be performed at the health department. VDH funding does not support additional cost for blood draws or administrative expenses; therefore, if clients are referred to a LabCorp drawing location, the cost of the blood draw must be paid with local funds.

## **Chlamydia/Gonorrhea Testing**

### **Nucleic Acid Amplification Testing**

Nucleic Acid Amplification Testing (NAAT) represents a significant advancement in chlamydia/gonorrhea (CT/GC) screening, previously culture, a test with comparatively poor sensitivity, was required to diagnose. FDA approval for this test is limited to genital specimens; however, research demonstrates the CT/GC NAAT is acceptable for testing extragenital specimens. Because this use of the CT/GC NAAT test is not FDA approved, each laboratory must conduct analytical validation of their methodology. LabCorp completed validation for extragenital NAAT and, per state contract, provides diagnostic testing for local health departments. Specimens for screening may be obtained for any, or all, of the following anatomical sites: genital (urine, vaginal, endocervical), pharyngeal, and/or rectal. A period of four weeks must elapse between a positive screening test

or treatment for CT/GC and a subsequent test for re-exposure, regardless of the anatomical site. This is due to the high sensitivity of the tests.

A test-of-cure is not needed for persons who receive a diagnosis of uncomplicated urogenital or rectal chlamydia or gonorrhea who are treated with any of the recommended or alternative regimens; however, any person with pharyngeal gonorrhea who is treated with an alternative regimen should return 14 days after treatment for a test-of cure using either culture or NAAT. If the NAAT is positive, effort should be made to perform a confirmatory culture before retreatment. All positive cultures for test-of-cure should undergo antimicrobial susceptibility testing<sup>1</sup>.

If a patient needs testing for an additional non-reportable condition, such as Trichomoniasis, an additional specimen must be collected and submitted using the “General Account” requisition form.

LabCorp test numbers (at the time of developing this manual):

- 183305 CT/GC Amplified-Urine
- 183323 CT/GC Amplified-Cervix
- 183357 CT/GC Amplified-Vaginal
- 183528 CT/GC Amplified-Throat
- 183449 CT/GC Amplified-Rectum

The price is currently \$10.00/specimen.

The cobas® PCR Media Dual Swab Sample Packet (Figure 1) is used for endocervical swabs only; the larger cotton tipped swab should be used to clean the mucous from the cervix and the smaller, brush-like swab should be used to submit the specimen. The PCR Uni Swab Packet is used for rectal, urethral, vaginal, and pharyngeal specimen collection. Specimens sent using the incorrect swab will be rejected by the lab.

**Figure 1: cobas® PCR Media Dual Swab Sample Packet**



**Figure 2: cobas® PCR Urine Sample Packet**



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<sup>1</sup> 2015 Sexually Transmitted Disease Treatment Guidelines: Gonococcal Infections. <https://www.cdc.gov/std/tg2015/gonorrhea.htm>

**Figure 3: cobas® PCR Media Uni Swab Sample Packet**



### Specimen Collection

Self-collection, particularly for rectal specimens, increases the uptake of testing and offers high acceptance among MSM. Self-collection can eliminate access barriers such as stigma, shame, negative interactions with service providers, and concerns about privacy and confidentiality. Published clinical research indicates self-collected specimens have equivalent or better detection rates for rectal, vaginal, and pharyngeal CT/GC compared to clinician collection.<sup>2,3</sup> It is important when collecting specimens to avoid cross contamination; cross contamination can make the test falsely positive.

### Urine Specimen Collection

Research evidence indicates the performance of male first catch urine samples is equivalent to, and in some situations superior to, urethral swabs. In men, the use of urine samples is highly acceptable and may improve the likelihood of uptake of routine screening.

Clients who provide urine samples for a CT/GC screening must:

- Have not urinated in the past hour; and
- Have not had a positive lab test or been treated for CT or GC in past 4 weeks.



Transgender males who have had sex reassignment surgery should collect a urine specimen.

Transgender males who have not had sex reassignment surgery may self-collect a vaginal swab or collect a urine specimen. Urine specimens are acceptable, but may miss up to 10% of infections compared to vaginal swabs.

Transgender females with or without a history of sex reassignment surgery should collect a urine specimen<sup>4</sup>.

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<sup>2</sup> van der Helm JJ, Hoebe CJ, van Rooijen MS, et al. High performance and acceptability of self-collected rectal swabs for diagnosis of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in men who have sex with men and women. *Sex Transm Dis*. 2009;36:493-497.

<sup>3</sup> Lunny C, Taylor D, Hoang L, et al. Self-collected versus clinician-collected sampling for chlamydia and gonorrhea screening: A systematic review and meta-analysis. *PLoS ONE*. 2015;10:1-23.

<sup>4</sup> 2018 UK national guideline for the management of infection 2 with *Neisseria gonorrhoeae*. Retrieved from <https://www.bashhguidelines.org/media/1195/gc-draft-for-consultation.pdf>.

Any female who has had a hysterectomy should collect a urine specimen. Without a ureters/cervix, there will not be sloughed endocervical cells in the vaginal vault for adequate testing<sup>5</sup>.

- Label the specimen collection cup. It may be helpful to mark the volume required on the specimen cup.
- Review the collection process with the client. Instruct them to collect 10 – 50mL of first catch urine and secure the lid. For best results, female patients should not cleanse the labial area prior to collection.
- While the urine specimen in the collection cup can be stored at 2°C to 30°C for up to 24 hours, it should be transferred to the urine specimen kit as soon as possible.
- Transfer the urine into the cobas® PCR Urine tube using the provided disposable pipette. The correct volume of urine has been added when the fluid level is between the two black lines on the tube label.
- Tightly re-cap the cobas® PCR Urine tube.
- Invert the tube five times to mix; the specimen is now ready for transport.

### Vaginal Specimen Collection

First catch urine from women, while acceptable for screening, might detect up to 10% fewer infections when compared with vaginal and endocervical swab samples.<sup>6</sup>

Clients who provide urine samples for a CT/GC screening must:

- Have not had a positive lab test or been treated for CT or GC in past 4 weeks.

Transgender males who have not had sex reassignment surgery may self-collect a vaginal swab or collect a urine specimen. Urine specimens are acceptable, but may miss up to 10% of infections compared to vaginal swabs<sup>6</sup>.



- Label the specimen collection tube.
- Review the collection process with the client and instruct them to collect the vaginal specimen, put the swab inside the specimen collection tube, align score line with the top edge of the tube, carefully break the swab shaft, seal the tube, and return the sealed tube.
- Given adequate instruction, self-collection of a vaginal specimen is equivalent to, or better than, clinician collection.<sup>7,8</sup>
- Diagrams may be posted for patient reference.
- Visually inspect the swab to assure there is evidence of use, the preservative liquid is still in the tube, and the lid on the specimen collection tube is tight to prevent spillage.
- Vaginal specimens may be collected during menstruation.
- Clinicians may collect a specimen during physical exam in lieu of self-collection, if desired.

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<sup>5</sup> Medscape. Sexually Transmitted Diseases. Retrieved from [https://www.medscape.com/viewarticle/458822\\_4](https://www.medscape.com/viewarticle/458822_4).

<sup>6</sup> Centers for Disease Control and Prevention. Recommendations for the Laboratory-Based Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. *MMWR* March 14, 2014;63:2.

<sup>7</sup> Sexton ME, Baker JJ, Nakagawa K, et al. How reliable is self-testing for gonorrhea and chlamydia among men who have sex with men? *J Fam Pract.* 2013;62:70-78.

<sup>8</sup> Freeman AH, Bernstein KT, Kohn RP, et al. Swabs for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* pharyngeal infection among men who have sex with men. *Sex Transm Dis.* 2011;38:1036-1039.

## Extragenital Testing

Extragenital screening is critically important, particularly among some high-risk populations: **77% of CT and 95% of GC infections are missed** among men who have sex with men (MSM) if screening is only performed at urethral sites.<sup>9</sup> Symptoms of rectal and pharyngeal CT/GC are nonspecific and often silent. In fact, 85% of rectal CT/GC infections are asymptomatic in MSM.<sup>10</sup>

### Rectal Specimen Collection

- Label the specimen collection tube.
- Review the collection process with the client and instruct them to collect the rectal specimen, put the swab inside the specimen collection tube, align score line with the top edge of the tube, carefully break the swab shaft, seal the tube, and return the sealed tube.
- Given adequate instruction, self-collection of a rectal specimen is equivalent to, or better than, clinician collection.<sup>11,12</sup>
- Diagrams may be posted for patient reference.
- Visually inspect the swab to assure there is evidence of use and the swab is not contaminated with significant fecal matter, the preservative liquid is still in the tube, and the lid on the specimen collection tube is tight to prevent spillage.
- Clinicians may collect a specimen during physical exam in lieu of self-collection, if desired.



### Pharyngeal Specimen Collection

- Label the specimen collection tube.
- Given adequate instruction, self-collection of a pharyngeal specimen is equivalent to, or better than, clinician collection.<sup>13,14</sup>
- The swab should make contact with the key areas of the throat: uvula and left/right posterior walls and tonsils.<sup>15</sup>
- Diagrams may be posted for patient reference.
- Some patients prefer clinician collection. The same collection technique of making contact with the key areas of the throat: uvula and left/right posterior walls and tonsils should be observed. An instructional video is available at <https://www.youtube.com/watch?v=KJtqxvAstCo>.



<sup>9</sup> Marcus JL, Bernstein KT, Kohn RP, et al. Infections missed by urethral-only screening for chlamydia or gonorrhea detection among men who have sex with men. *Sex Transm Dis*. 2011;38:922-924.

<sup>10</sup> Kent CK, Chaw JK, Wong W, et al. Prevalence of rectal, urethral, and pharyngeal chlamydia and gonorrhea detected in 2 clinical settings among men who have sex with men: San Francisco, California, 2003. *Clin Infect Dis*. 2005;41:67-74.

<sup>11</sup> Sexton ME, Baker JJ, Nakagawa K, et al. How reliable is self-testing for gonorrhea and chlamydia among men who have sex with men? *J Fam Pract*. 2013;62:70-78.

<sup>12</sup> Freeman AH, Bernstein KT, Kohn RP, et al. Swabs for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* pharyngeal infection among men who have sex with men. *Sex Transm Dis*. 2011;38:1036-1039.

<sup>13</sup> Sexton ME, Baker JJ, Nakagawa K, et al. How reliable is self-testing for gonorrhea and chlamydia among men who have sex with men? *J Fam Pract*. 2013;62:70-78.

<sup>14</sup> Freeman AH, Bernstein KT, Kohn RP, et al. Swabs for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* pharyngeal infection among men who have sex with men. *Sex Transm Dis*. 2011;38:1036-1039.

<sup>15</sup> San Francisco City Clinic. Patient instructions for self-collected specimens: pharyngeal and rectal. Available at: <http://www.sfcityclinic.org/providers>.



### Gonorrhea Culture

Gonorrhea culture testing is required to evaluate suspected cases of gonorrhea treatment failure.

LabCorp test numbers (at the time of developing this manual):

- 008128 GC Culture Only SOURCE: \_\_\_\_\_
- 182537 GC Culture, Pharyngeal
- 182526 GC Culture, Rectal

Currently the price is \$8.05/specimen.

The COPAN® Transystem Sterile Transport Swab (Figure 3) should be used for all GC culture tests.

**Figure 3: COPAN® Transystem Sterile Transport Swab**



### Resistance Testing

GC Resistance testing is available to monitor developing resistance to current treatment regimens.

LabCorp test numbers (at the time of developing this manual):

- 183130 Susceptibility, N. gonorrhoeae

Currently the price is \$3.50 per specimen.

The COPAN® Transystem Sterile Transport Swab (Figure 3) should be used for all sensitivity tests.

**Figure 4: COPAN® Transystem Sterile Transport Swab**



### Syphilis Testing

#### Screening Cascade

The screening test for syphilis available through LabCorp is the T Pallidum Screening Cascade, which uses the reverse sequence screening. The first test that is conducted is a CIA, if it is positive, a quantitative RPR is conducted; if the RPR is negative, a TPPA is conducted. See [Attachment G](#) for the Syphilis Testing Algorithm.

Some potential reasons for false positives are available at: <https://www.cdc.gov/std/tg2015/syphilis.htm>. Centrifuge within two hours of collection. The test requires **5mL serum** in the gold top collection tube.

LabCorp test numbers (at the time of developing this manual):

- 183379                      T Pallidum Screening Cascade

**Figure 5: Plastic serum separator (5 mL BD Gold top) collection tube**



### RPR

A standalone **RPR** can be requested on the OEPI account. The RPR should only be used for post-treatment titers; the RPR is NOT a screening or diagnostic test. The RPR test requires **1mL serum** in red-top or gel-barrier tube.

LabCorp test numbers (at the time of developing this manual):

- 006072                      RPR

The current price of the RPR is \$1.25.



### HIV Testing

The screening test for HIV available through LabCorp is the HIV 1/0/2 4<sup>th</sup> Generation, which automatically reflexes if necessary. Additional information regarding HIV testing is available at: <http://vdhweb.vdh.virginia.gov/epidemiology/divisions-and-programs/division-of-disease-prevention/hiv-testing/>.

LabCorp test number (at the time of developing this manual):

- 083935                      Panel 083935

Currently the price is \$5.00 per specimen if the tests does not reflex. If it reflexes to the HIV 1/2 AB Differentiation, an additional cost of \$27.00 is added per specimen.



2 mL of serum is needed in a gel-barrier tube with red/gray-mottled top or red-top tube.

### Hepatitis Testing

Both Hepatitis B and C tests reflex automatically if necessary. Additional information about eligibility and test interpretation is available at <http://vdhweb.vdh.virginia.gov/epidemiology/divisions-and-programs/division-of-disease-prevention/hepatitis-testing/hepatitis-resources/>.

### Hepatitis A

The OEPI account does not cover any tests for Hepatitis A. Clinics should recommend the Hepatitis vaccine; contact the VDH Immunization Program for more information: <http://www.vdh.virginia.gov/immunization/>.

### Hepatitis B

Use the OEpi LabCorp requisition form to request a HBV combo test (HBsAb+HBcAb+HBsAg) with reflex to IgM test for patients who meet at least one defined criteria and are uninsured or non-chargeable.

LabCorp test number (at the time of developing this manual):

- 219949                      Hepatitis Panel Reflex to IGM, HBcAb+HBsAb+Ag

Currently the price is \$10.95 per specimen if the tests does not reflex. If it reflexes to the HBcIgM, an additional cost of \$6.00 is added per specimen.

Blood specimen collection supplies and requirements for serum (HBV combo test):

- Collection media: 10 mL red-top tube or gel-barrier tube
- Volume: 7 mL of serum is the minimum amount required to run the HBV combo test
- Specimen storage instructions: room temperature
- Sample stability: 14 days at room temperature, refrigerated or frozen and three freeze/thaw cycles



### Hepatitis C

Use the OEpi LabCorp requisition form to request a HCV Antibody reflex to NAA (LabCorp test number 144045) for patients who meet the defined criteria and are uninsured or non-chargeable (e.g., reactive rapid HCV antibody test from a VDH-affiliated testing site). The “reflex to NAA” indicates that if the HCV Ab is positive, LabCorp will automatically test for HCV RNA via nucleic acid amplification (NAA). HCV RNA is the confirmatory test. Other hepatitis C tests are not authorized on the account. If an alternative test is clinically indicated, contact the viral hepatitis testing coordinator for assistance.

LabCorp test number (at the time of developing this manual):

- 144045                      HCV Antibody reflex to NAA

Currently the price is \$6.80 per specimen if the tests does not reflex. If it reflexes to the HCV RNA NAA, an additional cost of \$85.00 is added per specimen.

Blood specimen collection supplies and requirements for HCV conventional blood draw testing:

- Container: Red-top tube or gel-barrier tube
- Collection: If tube other than a gel-barrier tube is used, transfer separated serum to a plastic transport tube. Do not freeze gel-barrier tube (pour off serum first)



- Volume: 3mL of serum is the required minimum to run the test; 5mL is preferred
- Specimen storage instructions: Refrigerate
- Stability Requirements: 3 days room temperature; 14 days refrigerated and frozen; three freeze/thaw cycles

### Hemoglobin A1c

The Hemoglobin A1c test is available on the Office of Epidemiology requisition form for suspected Tuberculosis (TB) cases. Additional information on the TB program is available at:

<http://www.vdh.virginia.gov/tuberculosis-and-newcomer-health/tuberculosis/>.

LabCorp test number (at the time of developing this manual):

- 001453 Hemoglobin A1c

Currently the price is \$2.85 per specimen.

4 mL of whole blood is needed in a Lavender-top (EDTA) tube, green-top (lithium heparin) tube, or gray-top (sodium fluoride) tube.

### Additional Testing

Additional testing for infections such as Trichomoniasis, HPV, Pap tests, and bacterial vaginosis are not covered by the OEPI account. These tests should be charged to a patient's insurance or covered by the LHD's General Account.

### Labeling Specimens

- Affix a sticker label to the specimen collection tube with the following information:
  - Name (must be an exact match to the lab requisition);
  - Date of birth;
  - Date of specimen collection;
  - Specimen type;
  - LabCorp test number; and
  - Additional patient identifier, if available (e.g., WebVision number).
- Do not cover the expiration date on the specimen collection tube with the sticker label.
- See Attachment I for additional information.

### Adding Tests after the Specimen Has Been Collected

If you have a [LabCorp Link™ login/password](#), you can submit your add-on test request electronically. You may also call your local laboratory and add-on the test request. After the verbal add-on order, you will receive a request for written authorization for the verbal order and LabCorp will provide a fax number to send this form back to the laboratory with signature and any other additional information that is required.

### Submission Issues that Delay Testing or Prompt Rejections

The following are some common reasons for rejections by the laboratory. Additional reasons that would prompt rejection are available at <https://www.labcorp.com/resource/introduction-to-specimen-collection>.

1. Incorrect swab or tube used to collect specimen.

2. Missing or inconsistent patient name; patient name on the specimen collection tube label and the lab requisition form must be consistent. Use printed specimen tube labels whenever possible and put identical labels on all locations.
3. Incorrect or missing specimen source on the specimen collection tube label and/or the lab requisition form.
4. Missing or inconsistent collection date listed on the specimen collection tube label and/or the lab requisition form.
5. Missing indication of “requested test” on the lab requisition form.
6. Use of whiteout on specimen tube label or lab requisition form. Mistakes must be corrected by marking a line and rewriting the correct information above or beside it. Any evidence of whiteout will prompt rejection.
7. Missing or broken foil top of specimen tube; the foil must be intact to preserve the sample integrity. The caps on the specimen tube must be tight to prevent spillage of the preservative.

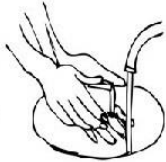
## Attachment A – Self Collection of Rectal Swab for CT/GC (English)

### Self-Collection of Rectal Swab

ATTENTION: Read ALL instructions before you begin!



**STEP 1**  
Wash your hands thoroughly.



**STEP 2**  
Open the wrapper and remove the swab with the cotton tip.



Do **not** touch the tip of the swab.

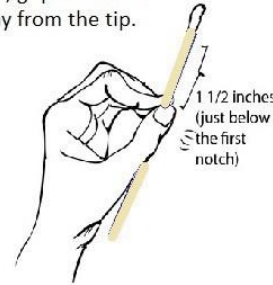
**STEP 3**



Pull underwear down or off. Squat down, or lift one leg up on a ledge, toilet, or chair.

**STEP 4**

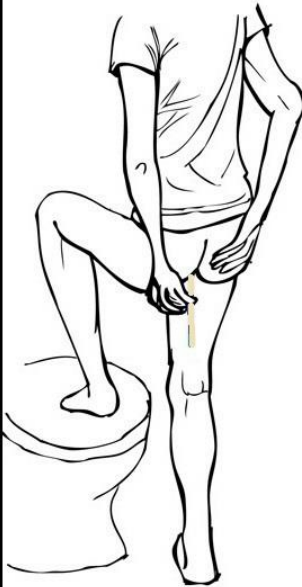
With one hand, grip the swab 1.5 inches away from the tip.



Do **NOT** use any kind of lubricant (soap, saliva, etc) on either the swab or your body.

**STEP 5**

Use your other hand to lift one cheek for easy access to the rectum.



**STEP 6**  
Insert the swab 1.5 inches into your rectum until you feel your fingers touch your anus.

**STEP 7**  
Once the swab is in, walk your fingers halfway down the swab (away from your body) and grip it there for stability.

**STEP 8**  
Gently turn the swab clockwise for about 30 seconds.

**STEP 9**  
When removing the swab from your rectum, slowly turn it in a circle while pulling it out.

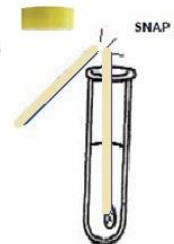
**STEP 10**

Uncap tube and keep upright - do not pour out the clear liquid. Place the swab into the tube.



**STEP 11**

Align the score line with the top edge of the tube and carefully break the shaft of the swab.



**STEP 12**

Swab will drop to the bottom of the tube. Screw cap on tightly so it doesn't leak.



**STEP 13**

Wash your hands thoroughly.



**STEP 14**

Return the tube to your health care provider.





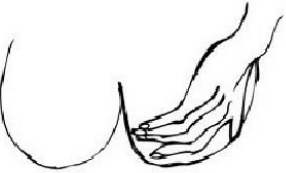
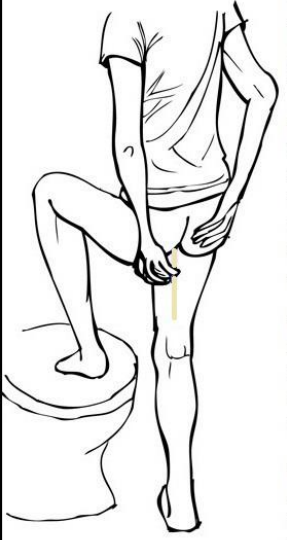

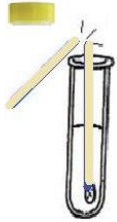

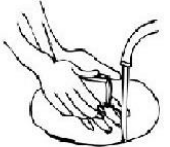


## Attachment B – Self Collection of Rectal Swab for CT/GC (Spanish)

### Auto Coleccion de Muestra Rectal

Importante: ¡Lea estas instrucciones antes de comenzar!



<p><b>Paso 1</b> Lávese bien las manos.</p>  <p><b>Paso 2</b> Abra el envoltorio y retire el hisopo con punta de algodón.</p>  <p>No toque la punta del hisopo.</p>	<p><b>Paso 3</b> Baje su ropa interior, agachese o levante una pierna y pongala en una repisa, inodoro o una silla.</p> 	<p><b>Paso 4</b> Con su mano, agarre el hisopo, dejando una pulgada y media (1.5") libre entre sus dedos y la punta del hisopo con algodón. NO utilice ningún tipo de lubricante (jabón, saliva, etcetera) en el hisopo ni en su recto.</p>  <p>1.5 pulgadas (justo debajo de la primera muesca)</p>	<p><b>Paso 5</b> Utilice su otra mano para abrir un poco mas su trasero y facilitar el acceso del hisopo en su recto.</p> 
 <p><b>Paso 6</b> Inserte el hisopo una pulgada y media (1.5") dentro de su recto hasta sentir sus dedos tocar su ano.</p> <p><b>Paso 7</b> Una vez haya introducido el hisopo en su recto, mueva sus dedos hacia el lado opuesto de su ano, hasta la mitad del hisopo y sostengalo para que se mantenga estable mientras esta introducido en su recto.</p> <p><b>Paso 8</b> Suavemente y con cuidado gire el hisopo en círculos por aproximadamente 30 segundos, mientras aun este dentro de su recto.</p> <p><b>Paso 9</b> Al retirar el hisopo de su recto, gíre lo lentamente en un círculo mientras lo hala hacia fuera.</p>	<p><b>Paso 10</b> Destape el tubo y mantengalo en posición vertical en una superficie plana. NO tire el líquido claro que se encuentra adentro, y luego coloque el hisopo dentro del tubo.</p>  <p><b>Paso 11</b> Alinee la línea con el borde de la entrada del tubo y rompa con cuidado el eje del hisopo marcado con la hendidura.</p> 	<p><b>Paso 12</b> El hisopo con la punta de algodón debe ser introducido hasta el fondo del tubo. Vuelva a tapar firmemente el tubo dejando adentro el hisopo y el líquido.</p>  <p><b>Paso 13</b> Lávese muy bien las manos</p>  <p><b>Paso 14</b> Regrese el tubo con su muestra rectal a su proveedor de salud.</p>	

Attachment C – Self Collection of Pharyngeal Swab for CT/GC (English)

Self-Collection of Pharyngeal Swab

Attention: Read ALL instructions before you begin!



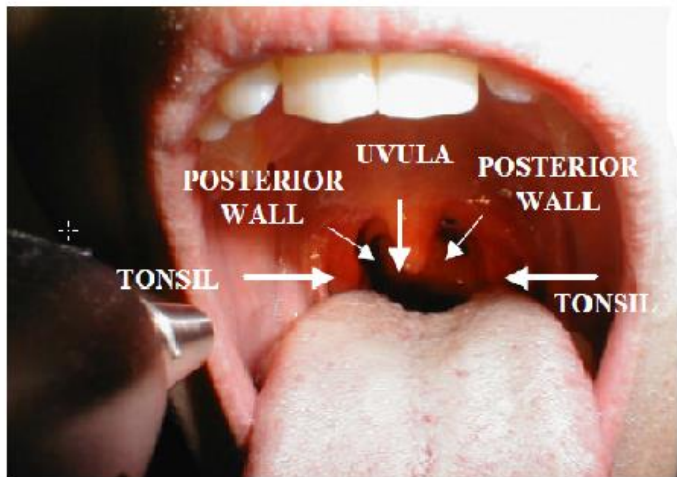
**Step 1.**

Wash your hands thoroughly.



**Step 2.** Open the wrapper and remove the swab with the cotton tip.

Do not touch the tip of the swab.

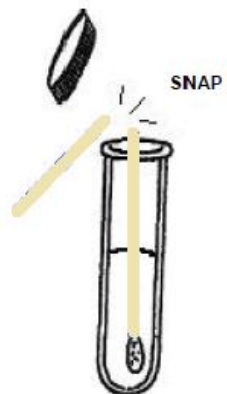


**Step 3.** Open mouth widely and touch the end of the swab to the 5 areas of the throat.

**Step 4.** Uncap tube and keep upright - do not pour out the clear liquid. Place the swab into the tube.



**Step 5.** Align the score line with the top edge of the tube and carefully break the shaft of the swab.



**Step 6.** Place cap back on the test tube and tighten (do not puncture the foil).



**Step 7.** Throw away wrapper

**Step 8.** Wash your hands thoroughly.



**Step 9.** Return the tube to your health care provider.



**Attachment D – Self Collection of Pharyngeal Swab for CT/GC (Spanish)**

**Auto-colección de muestra de la faringe**

Atención: ¡Lea todas las instrucciones antes de comenzar!



**Paso 1**

Lávese bien las manos.



**Paso 2**

Abra la envoltura y remueva el aplicador agarrándolo por la manga rosada. No toque el área del algodón.



**Paso 3**

Abra bien la boca y que el algodón toque las cinco áreas indicadas de la garganta.



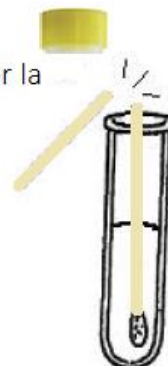
**Paso 4**

Remueva la tapa y mantenga el tubo de ensayo derecho. No vierta el líquido claro. Coloque el aplicador dentro del tubo.



**Paso 5**

Centralice el aplicador y pártalo cuidadosamente por la marca.



**Paso 6**

Coloque la tapa en el tubo de ensayo. Cuidado que no perfore (rompa) el papel de aluminio al cerrar el tubo.



**Paso 7**

Descarte la envoltura

**Paso 8**

Lávese bien las manos.



**Paso 9**





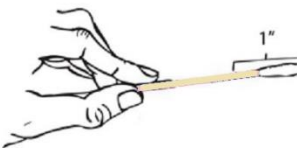


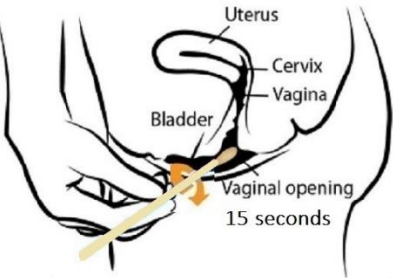




Devuelva el tubo a su proveedor médico.

## Attachment E – Self Collection of Vaginal Swab for CT/GC (English)

### Self-Collection of Vaginal Swab

ATTENTION: Read ALL instructions before you begin!







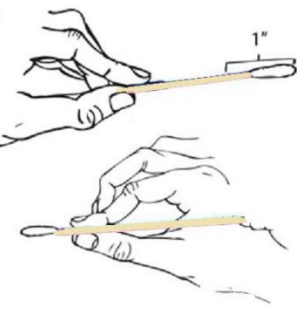



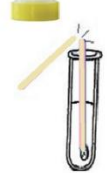


<p><b>STEP 1</b> Wash your hands thoroughly.</p>  <p><b>Step 2</b> Undress from the waist down. Get into a position where you can comfortably insert a swab into your vagina - such as sitting on the toilet, standing with one foot on a chair, or any position that you would use to insert a tampon.</p> 	<p><b>Step 3</b> Open the wrapper and remove the swab with the cotton tip.</p> <p>Do not touch the tip of the swab.</p> 	 <p><b>STEP 4</b> Insert the white tip of the swab about one inch inside the opening of your vagina.</p>  <p>1"</p>  <p>If it helps, you can grip the swab 1" away from the end of the soft tip, so your fingers will touch your body when the swab is in far enough.</p>
<p><b>Step 5</b> Rotate the swab for 15 seconds, making sure the swab touches the walls of your vagina so that moisture is absorbed into the swab.</p>  <p>15 Seconds</p>  <p>Uterus Cervix Vagina Bladder Vaginal opening 15 seconds</p> <p><b>STEP 6</b> Remove the swab from your vagina. Don't let the tip of the swab touch anything else.</p>	<p><b>Step 7</b> Uncap tube and keep upright (do NOT pour out the clear liquid). Place the swab into the tube.</p>  <p><b>STEP 8</b> Align the score line with the top edge of the tube and carefully break the shaft of the swab.</p>  <p>SNAP!</p> <p><b>STEP 9</b> Swab will drop to the bottom of the tube. Screw cap on tightly so it does not leak.</p>  <p><b>STEP 10</b> Wash your hands.</p>  <p><b>STEP 11</b> Return the tube to your health care provider.</p>	

## Attachment F – Self Collection of Vaginal Swab for CT/GC (Spanish)

### Auto recogida de hisopo vaginal

**Importante: ¡Lea estas instrucciones antes de comenzar!**

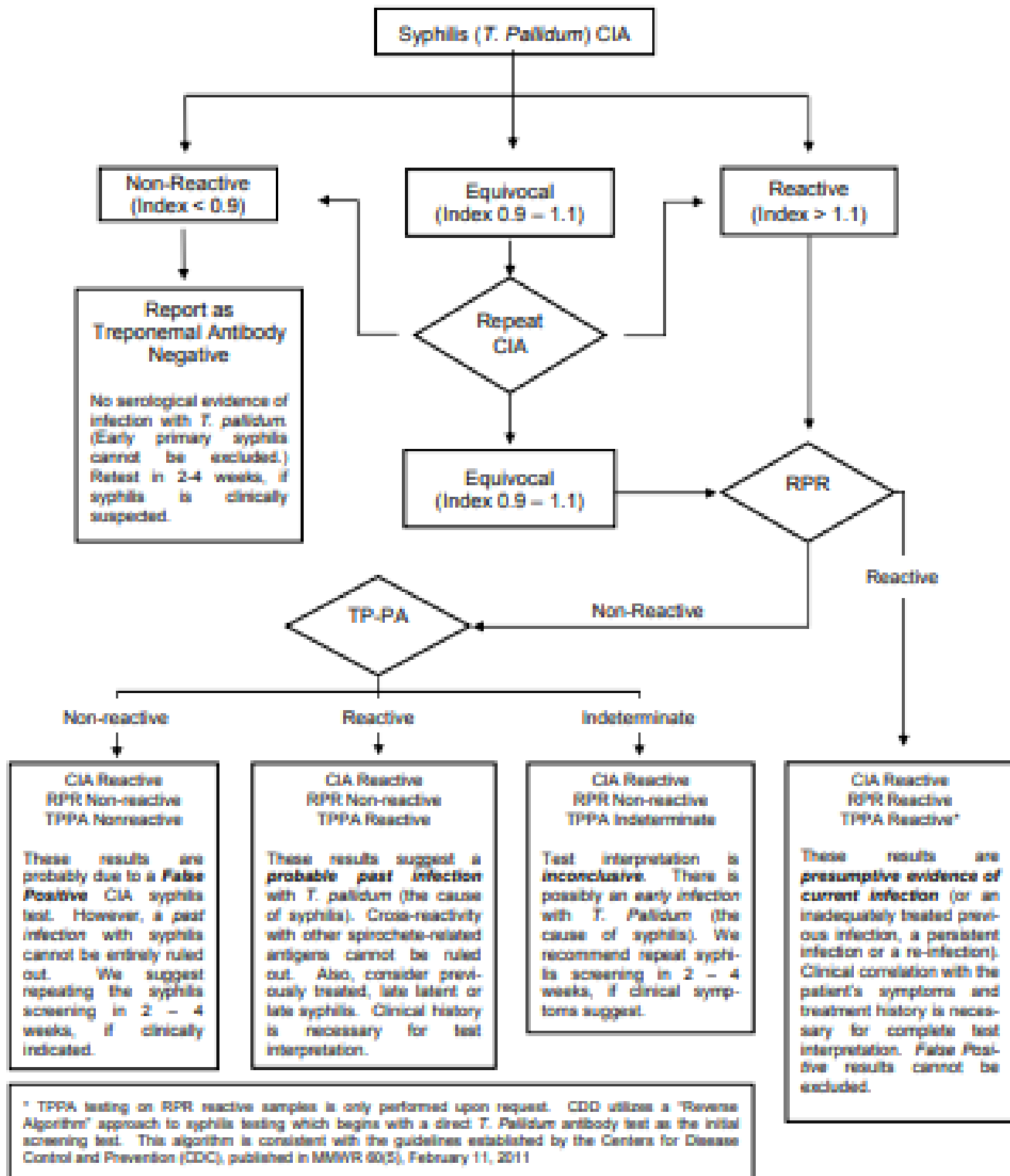


<p><b>Paso 1</b> Lávese bien las manos.</p>  <p><b>Paso 2</b> Desvístase de la cintura para abajo. Póngase en una posición cómoda para insertar el aplicador en la vagina. Puede sentarse en el inodoro, pararse y colocar la pierna en una silla, o acomodarse en la posición que usaría para colocarse un tampón.</p> 	<p><b>Paso 3</b> Abra la envoltura y remueva el aplicador agarrándolo por la manga blanca. No toque el área del algodón.</p> 	 <p><b>Paso 4</b> Introduzca la parte del aplicador con algodón como hasta una pulgada dentro de la vagina.</p>  <p>Si le ayuda, puede agarrar el aplicador a una pulgada del algodón de manera que sus dedos tocarán su cuerpo cuando el aplicador esté a la distancia deseada.</p>
<p><b>Paso 5</b> Rote (gire) el aplicador por 15 segundos. Asegúrese que el algodón toque las paredes de la vagina de manera que pueda absorber la humedad en ella.</p>  <p>15 segundos</p>  <p>15 segundos</p> <p><b>Paso 6</b> Remueva el aplicador de la vagina. No permita que el algodón toque cualquier otra superficie.</p>	<p><b>Paso 7</b> Remueva la tapa y mantenga el tubo de ensayo derecho. No vierta el líquido claro. Coloque el aplicador dentro del tubo.</p>  <p><b>Paso 8</b> Centralice el aplicador y pártalo cuidadosamente por la marca.</p>  <p><b>Paso 9</b> Coloque la tapa en el tubo de ensayo. Cuidado que no perfore (rompa) el papel de aluminio al cerrar el tubo.</p>  <p><b>Paso 10</b> Lávese bien las manos.</p>  <p><b>Paso 11</b> Devuelva el tubo a su proveedor médico.</p>	

## Attachment G – Syphilis Testing Algorithm

Title: Syphilis Testing Algorithm (Reverse Algorithm)

Number: AL0126.04.A





## Attachment I: Proper Specimen Identification & Labeling

# Proper Specimen Identification & Labeling

### Positive Specimen Identification

According to LabCorp's laboratory accreditation agency, all primary specimen containers must be labeled with 2 identifiers at the time of collection.

In order for a specimen to be considered to have positive identification, the test request form (TRF) and each related specimen container must contain exactly the same name and unique patient identifier.

Examples of acceptable identifiers include, but are not limited to, the following:

- Patient's name
- Patient's date of birth
- Patient's Social Security number
- Hospital number
- Requisition number
- Accession number
- Unique random number

A location (eg, hospital room number) is not an acceptable identifier.



### Specimen Labeling

Use of LabCorp-provided specimen collection containers is always advised. Contact your local LabCorp Service Representative for collection devices. In many cases, the collection devices and labels provided by LabCorp are selected to be used in conjunction with LabCorp's automated laboratory systems.

Labels placed on containers that were not provided by LabCorp may have to be trimmed to accommodate our analyzers.



## Attachment I: Requirements for Test Request Forms

## REQUIREMENTS FOR TEST REQUEST FORMS

## Providing complete information saves valuable time — fewer phone calls, letters, and follow-up.

The billing option (insurance, client, patient, Medicare, Medicaid) must be indicated on every test request form. For billing to third-party payors, please provide a copy of the front and back of the insurance card.

### Private Insurance/Managed Care

- Patient Legal Name (Last, First, MI)
- Patient Gender
- Patient Date of Birth
- Time Collected
- Date Collected
- NPI
- Physician Last and First Name
- ICD-CM Diagnosis Codes  
(in format in effect at date of service and at highest specificity)
- Patient Address  
(city, state, and ZIP code)
- Patient Telephone #, w/area code
- Policy Holder/Responsible Party – if different from patient
- Primary Billing Party – complete insurance information
- Secondary Billing Party – complete insurance information as applicable to patient
- Authorized Signature for Medical Release

### Requirements for Private Insurance/Managed Care Bill

Fields highlighted in blue are required for private insurance/managed care billing. Fields not highlighted may be necessary for certain types of testing or to meet individual payor-specific requirements. Please provide a copy of the front and back of the insurance card.

Patient's Legal Name (Last, First, MI)		Sex	Date of Birth	Collection Time	Fasting	Collection Date	Urine Invol
NPI		UPIN	Physician's ID #	Patient's SS #		Patient's ID #	
Physician's Name (Last, First)		Physician's Signature		Hospital Patient Status: <input type="checkbox"/> In-Patient <input type="checkbox"/> Out-Patient <input type="checkbox"/> Non-Patient			
Diagnosis/Symptoms in ICD-CM format in effect at Date of Service		Patient's Address		Phone		City State ZIP	
PRIMARY BILLING PARTY		SECONDARY BILLING PARTY		Name of Policy Holder (if different from patient)			
Insurance Carrier *		Insurance Carrier *		Address of Policy Holder			
ID #		ID #		APT #			
Group #		Group #		City State ZIP			
Insurance Address		Insurance Address		City State ZIP			
Name of Insured Person		Name of Insured Person		City State ZIP			
Relationship to Patient		Relationship to Patient		City State ZIP			
Employer Name		Employer Name		City State ZIP			
* Medicaid State		Physician's Provider #		* Yes <input type="checkbox"/> No <input type="checkbox"/>			

\*To view a list of Insurance providers filed by LabCorp (by state), visit [www.LabCorp.com](http://www.LabCorp.com), click on "I am a Health Care Provider," select the Resources tab, then Insurance Lists.

### Client Bill

- Patient Legal Name (Last, First, MI)
- Patient Gender
- Patient Date of Birth
- Time Collected
- Date Collected
- Physician Last and First Name

#### Optional

- Physician ID#
- Patient ID#

### Requirements for Client Bill

Fields highlighted in blue are required for client billing. Light yellow fields are optional. Fields not highlighted may be necessary for certain types of testing.

Patient's Legal Name (Last, First, MI)		Sex	Date of Birth	Collection Time	Fasting	Collection Date	Urine Invol
NPI		UPIN	Physician's ID #	Patient's SS #		Patient's ID #	
Physician's Name (Last, First)		Physician's Signature		Hospital Patient Status: <input type="checkbox"/> In-Patient <input type="checkbox"/> Out-Patient <input type="checkbox"/> Non-Patient			
Diagnosis/Symptoms in ICD-CM format in effect at Date of Service		Patient's Address		Phone		City State ZIP	
PRIMARY BILLING PARTY		SECONDARY BILLING PARTY		Name of Policy Holder (if different from patient)			
Insurance Carrier *		Insurance Carrier *		Address of Policy Holder			
ID #		ID #		APT #			
Group #		Group #		City State ZIP			
Insurance Address		Insurance Address		City State ZIP			
Name of Insured Person		Name of Insured Person		City State ZIP			
Relationship to Patient		Relationship to Patient		City State ZIP			
Employer Name		Employer Name		City State ZIP			
* Medicaid State		Physician's Provider #		* Yes <input type="checkbox"/> No <input type="checkbox"/>			



## REQUIREMENTS FOR TEST REQUEST FORMS

**Providing complete information saves valuable time — fewer phone calls, letters, and follow-up.**

### Patient Bill

- Patient Legal Name (Last, First, MI)
- Patient Gender
- Patient Date of Birth
- Time Collected
- Date Collected
- Physician Last and First Name
- Patient Address (city, state, and ZIP code)
- Patient Telephone #, w/area code

### Requirements for Patient Bill

Fields highlighted in blue are required for patient billing. Fields not highlighted may be necessary for certain types of testing.

Patient's Legal Name (Last, First, MI)		Sex	Date of Birth	Collection Time	Fasting	Collection Date	Urine (m/vol)
NPI		UPIN	Physician's ID #	Patient's SSN #	Patient's ID #		
Physician's Name (Last, First)		Physician's Signature		Hospital Patient Status: <input type="checkbox"/> In-Patient <input type="checkbox"/> Out-Patient <input type="checkbox"/> Non-Patient			
Diagnosis/Signs/Symptoms in ICD-CM format in effect at Date of Service		Highest Specificity REQUIRED		Patient's Address			
				City State ZIP			
PRIMARY BILLING PARTY		SECONDARY BILLING PARTY		Name of Policy Holder (if different from patient)			
Insurance Carrier *	Insurance Carrier *			Address of Policy Holder			
ID #	ID #			City State ZIP			
Group #	Group #			APT #			
Insurance Address	Insurance Address			City State ZIP			
Name of Insured Person	Name of Insured Person			Patient's Signature			
Relationship to Patient	Relationship to Patient			Patient's Signature			
Employer Name	Employer Name			MEDICARE ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN)			
Is Medicaid State	Physician's Provider #	Physician's Comp		Refer to Determining Necessity of ABN Completion on reverse			

### Medicare

- Patient Legal Name (Last, First, MI)
- Patient Gender
- Patient Date of Birth
- Time Collected
- Date Collected
- NPI
- Physician Last and First Name
- ICD-CM Diagnosis Codes (in format in effect at date of service and at highest specificity)
- Patient Address (city, state, and ZIP code)
- Patient Telephone #, w/area code
- Primary Billing Party – complete Medicare information
- Secondary Billing Party – complete insurance information as applicable to patient
- Authorized Signature for Medical Release
- Note: ABN information on reverse of TRF

### Requirements for Medicare Bill

Fields highlighted in blue are required for Medicare billing. Fields not highlighted may be necessary for certain types of testing. Please provide a copy of the front and back of the insurance card.

Patient's Legal Name (Last, First, MI)		Sex	Date of Birth	Collection Time	Fasting	Collection Date	Urine (m/vol)
NPI		UPIN	Physician's ID #	Patient's SSN #	Patient's ID #		
Physician's Name (Last, First)		Physician's Signature		Hospital Patient Status: <input type="checkbox"/> In-Patient <input type="checkbox"/> Out-Patient <input type="checkbox"/> Non-Patient			
Diagnosis/Signs/Symptoms in ICD-CM format in effect at Date of Service		Highest Specificity REQUIRED		Patient's Address			
				City State ZIP			
PRIMARY BILLING PARTY		SECONDARY BILLING PARTY		Name of Policy Holder (if different from patient)			
Insurance Carrier *	Insurance Carrier *			Address of Policy Holder			
ID #	ID #			City State ZIP			
Group #	Group #			APT #			
Insurance Address	Insurance Address			City State ZIP			
Name of Insured Person	Name of Insured Person			Patient's Signature			
Relationship to Patient	Relationship to Patient			Patient's Signature			
Employer Name	Employer Name			MEDICARE ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN)			
Is Medicaid State	Physician's Provider #	Physician's Comp		Refer to Determining Necessity of ABN Completion on reverse			

## REQUIREMENTS FOR TEST REQUEST FORMS

**Providing complete information saves valuable time — fewer phone calls, letters, and follow-up.**

### Medicaid

- Patient Legal Name (Last, First, MI)
- Patient Gender
- Patient Date of Birth
- Time Collected
- Date Collected
- NPI
- Physician Last and First Name
- Physician's Signature
- ICD-CM Diagnosis Codes (in format in effect at date of service and at highest specificity)
- Patient Address (city, state, and ZIP code)
- Patient Telephone #, w/area code
- Primary Billing Party – complete Medicaid information
- List State Abbreviation
- Physician's State Assigned Provider #
- Authorized Signature for Medical Release

### Requirements for Medicaid Bill

Fields highlighted in blue are required for Medicaid billing. Fields not highlighted may be necessary for certain types of testing.

Patient's Legal Name (Last, First, MI)		Sex	Date of Birth	Collection Time	Fasting	Collection Date	Urine test/col
NO	DAY	YE	AM	PM	Yes	NO	NO
NPI		UPIN	Physician's ID #	Patient's SS #	Patient's ID #		
Physician's Name (Last, First)		Physician's Signature		Hospital Patient Status: <input type="checkbox"/> In-Patient <input type="checkbox"/> Out-Patient <input type="checkbox"/> Non-Patient			
Diagnosis/Symptoms in ICD-CM format in effect at Date of Service		Patient's Address		Prices			
Highest Specificity REQUIRED		City		State		ZIP	
		Name of Policy Holder (if different from patient)		APT #			
PRIMARY BILLING PARTY		SECONDARY BILLING PARTY		Address of Policy Holder			
Insurance Carrier *		Insurance Carrier *		City		State ZIP	
ID #		ID #		APT #			
Group #		Group #		State ZIP			
Insurance Address		Insurance Address		Name of Insured Person			
Name of Insured Person		Name of Insured Person		Relationship to Patient			
Relationship to Patient		Relationship to Patient		Employer Name			
Employer Name		Employer Name		Is Medicaid? State Physician's Provider #			
Is Medicaid? State		Physician's Provider #		Signature Group <input type="checkbox"/> Yes <input type="checkbox"/> No			
I hereby authorize the release of medical information stored in the device described herein and authorize payment directly to LabCorp. I agree to assume responsibility for payment of charges for laboratory services that are not covered by my health insurance.							
Patient's Signature _____ Date _____ (Refer to Determining Necessity of ABN Completion via reverse)							



## IMPORTANT REMINDERS FOR COMPLETING TEST REQUEST FORMS

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### Providing complete information saves valuable time—fewer phone calls, letters, and follow-up.

#### Required On All Test Request Forms

- Indicate billing option (eg, private insurance/managed care [HMO], client, patient, Medicare, Medicaid)
- Patient's legal name (last, first, middle initial)
- Patient's gender and date of birth (can verify on driver's license)
- Date of service/collection date
- Patient's address and phone number with area code
- Ordering physician's name (last, first)
- NPI
- ICD-CM diagnosis code in format in effect at the date of service and at the highest level of specificity (ie, include fourth or fifth digit when appropriate)

**Do not** provide a "rule-out diagnosis"; instead, provide a diagnosis code based on the signs or symptoms of the patient on the particular date of service (see page 25).

#### Private Insurance/ Managed Care (HMO)

*Please attach a copy of the front as well as the back of the insurance card.*

- Policy Holder's full name, if different from patient
- Policy Holder's address and phone number with area code
- Patient's relationship to Policy Holder
- Insurance company
  - Insurance claim address
  - Insured/contract/policy number, including prefixes or suffixes
  - Group number or name
- Ordering physician's NPI

#### Medicaid

*Please attach a copy of the front as well as the back of the card.*

- Patient's Medicaid number and state where Medicaid card is issued
- Ordering physician's NPI and state-specific Medicaid provider number and/or signature, if applicable

#### Medicare

*Please attach a copy of the card.*

- Medicare number including alpha prefix or suffix
- Ordering physician's NPI

*A properly executed ABN should always be obtained for limited coverage tests when the diagnosis does not support medical necessity or for tests deemed investigational.*

#### Patient Bill

If the person responsible for the charges is other than the patient, provide:

- Responsible party's name
- Responsible party's full address and phone number with area code

#### Please note:

These are general billing guidelines. Some billing options may require more or less information.

## HELP US HELP YOU

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- Use LabCorp test request forms to assure best turnaround time and specimen tracking.
- Correct specimen collection, transport, and careful completion of the specimen label ensures the best results. The accuracy of test results is dependent on the integrity of specimens. If you have questions, contact LabCorp customer service or refer to LabCorp's online Test Menu at [www.LabCorp.com](http://www.LabCorp.com).
- Use LabCorp test numbers when possible. Ambiguous orders must be clarified; this can cause delays in processing and increase wait times for your patients at LabCorp locations for specimen collection.
- Submit ICD-CM codes (in format in effect at the date of service and at the highest level of specificity) that support the diagnosis for the date of service.
- Implementation of ICD-10-CM is scheduled for October 1, 2014. ICD-10-CM information can be obtained from the following Web sites:
  - Centers for Medicare & Medicaid Services — <http://www.cms.gov/ICD10/>
  - LabCorp — <http://www.labcorp.com/icd10>
- Please provide up-to-date and complete insurance information and a copy of the patient's insurance card (front and back). Providing complete information saves valuable time — fewer phone calls, letters, and follow-up.
- When submitting biopsy specimens, include information about the site from which each sample was taken and the patient's history.

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Use the online Find a Lab feature for the most up-to-date list of specimen collection sites at [www.LabCorp.com](http://www.LabCorp.com) or by calling 888-LABCORP.

Research shows that 80% of patients visit patient service centers between the opening hour and 10:00 AM. If your patients do not require a fasting specimen, they appreciate knowing about off-peak hours. Hours of operation and contact information for specimen collection sites can be found on [www.LabCorp.com](http://www.LabCorp.com).

Appointments are preferred for glucose tolerance testing.

# LABCORP TEST REQUEST FORM REQUIREMENTS

<b>Check One</b> 03 <input type="radio"/> Client Bill 04 <input type="radio"/> Patient Bill 05 <input type="radio"/> Medicare, Traditional ST* <input type="radio"/> Medicaid, Traditional XI <input type="radio"/> Private Insurance/Managed Care ST* = State Abbreviation	Patient's Legal Name (Last, First, MI)		Sex	Date of Birth	Collection Time	Fasting	Collection Date	Uninsured/Not
	NPI		Physician's ID #	Patient's ID #	Hospital Patient Status			
	Physician's Name (Last, First)		Physician's Authorized Signature		Patient's Address		City State ZIP	
	Diagnosis/Symptoms in ICD-CM format in effect at Date of Service Highest Specificity REQUIRED		Name of Policy Holder (if different from patient)		Address of Policy Holder		APT #	
PRIMARY BILLING PARTY		SECONDARY BILLING PARTY		Name of Policy Holder		City State ZIP		MEDICARE ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN) Refer to Determining Necessity of ABN Completion on reverse.
Insurance Carrier *		Insurance Carrier *		City		State ZIP		
ID #		ID #		Name of Insured Person		Relationship to Patient		
Group #		Group #		Employer Name		Employer Name		
Insurance Address		Insurance Address		Name of Insured Person		Relationship to Patient		
Name of Insured Person		Name of Insured Person		Relationship to Patient		Relationship to Patient		
Relationship to Patient		Relationship to Patient		Employer Name		Employer Name		
Employer Name		Employer Name		Employer Name		Employer Name		
If Medicaid State		Physician's Provider #		Workers Comp		Other Code		

## Client Bill

- Billing Option
- Date Collected
- Time Collected
- Patient Legal Name (Last, First, MI)
- Patient Gender
- Patient Date of Birth
- Physician Last & First Name

## Optional

- Patient ID N°
- Physician ID N°

## Client

### + Patient

### + + + + + Medicare, Traditional

### + + + + + Medicaid, Traditional

### + + + + + Private Insurance/Managed Care

Fields not highlighted may be necessary for certain types of testing or to meet individual payor-specific requirements.

## Patient Bill

- Billing Option
- Date Collected
- Time Collected
- Patient Legal Name (Last, First, MI)
- Patient Gender
- Patient Date of Birth
- Patient Address (city, state, & ZIP code)
- Patient Telephone N°, with area code
- Physician Last & First Name

## Medicare, Traditional

- Billing Option
- Date Collected
- Time Collected
- Patient Legal Name (Last, First, MI)
- Patient Gender
- Patient Date of Birth
- Patient Address (city, state, & ZIP code)
- Patient Telephone N°, with area code
- Physician Last & First Name
- NPI
- Authorized Signature for Medical Release
- ICD-CM Diagnosis Codes (in format in effect at date of service and at highest specificity)
- ABN Signed & Dated when applicable (Refer to Instructions on back of test request form)
- Primary Billing Party - complete Traditional Medicare information
- Secondary Billing Party - complete insurance information as applicable to patient

## Medicaid, Traditional

- Billing Option
- Date Collected
- Time Collected
- Patient Legal Name (Last, First, MI)
- Patient Gender
- Patient Date of Birth
- Patient Address (city, state, & ZIP code)
- Patient Telephone N°, with area code
- Physician Last & First Name
- Physician Signature
- NPI
- Authorized Signature for Medical Release
- ICD-CM Diagnosis Codes (in format in effect at date of service and at highest specificity)
- Primary Billing Party - complete Traditional Medicaid information
- List State Abbreviation
- Physician's State Assigned Provider N°

## Private Insurance/Managed Care

- Billing Option
- Date Collected
- Time Collected
- Patient Legal Name (Last, First, MI)
- Patient Gender
- Patient Date of Birth
- Patient Address (city, state, & ZIP code)
- Patient Telephone N°, with area code
- Physician Last & First Name
- NPI
- Authorized Signature for Medical Release
- ICD-CM Diagnosis Codes (in format in effect at date of service and at highest specificity)
- Responsible Party, if different from patient
- Primary Billing Party - complete insurance information, specify if MC or MD HMO/PPO
- Secondary Billing Party - complete insurance information as applicable to patient



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## Optional

- Hospital Status